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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,580	09/12/2005	Patricia Lynne Conway	BSWV-P01-008	3799

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EXAMINER	
MARX, IRENE	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
07/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,580	CONWAY, PATRICIA LYNNE	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-11,14,15 and 33-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-11, 14-15 and 33-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/30/08 has been entered.

Claims 1, 4-11, 14-15 and 33-35 are being considered on the merits.

To conform with standard practice and for the sake of clarity, independent claims should be amended to start with --A-- and dependent claims to start with --The-.

The claims of record are not in compliance with the current rules. The claims must be in accordance with **Revised Amendment Format 37 CFR 1.121** (c).

Amendments to a claim must be made by rewriting the entire claim with all changes (e.g., additions and deletions) as indicated in this subsection, except when the claim is being canceled. **Each amendment document that includes** a change to an existing claim, **cancellation of an existing claim** or addition of a new claim, **must include a complete listing of all claims ever presented,** including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).

Claims 12 and 13 were omitted from the listing without providing the proper status identifiers and/or text.

The rejection under 35 U.S.C 112, regarding deposit is withdrawn in view of applicant's averments.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-7 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5-7 and 15 are vague, indefinite and confusing in their recitation of addition of prebiotics to "an organic component" as required by claim 4 in the alternative. Prebiotics are generally added to probiotic cultures.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4-6, 10-11, 14, and 33-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsuzaki *et al.* (U.S. Patent No. 5,601,999).

The claims are directed to an organic component of *Lactobacillus fermentum* variant and a pharmaceutically acceptable carrier obtained by disruption of a whole cell optionally in conjunction with an oligosaccharide.

The reference teaches an organic component of *Lactobacillus fermentum* comprising polysaccharides and glucans and a pharmaceutically acceptable carrier which is obtained by disruption of a whole cell. The composition is provided in conjunction with an oligosaccharide. See, e.g., Example 2.

That the strain disclosed in the reference has a different designation does not mean that the product produced by the strain differs from the instantly claimed product, which is directed to any organic component obtained by disruption of an ambiguous variant.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a Novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Furthermore, the composition is claimed as a product-by-process. Since the U.S. Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15

USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433.

The reference composition is provided as solutions, tablets or powders (col. 2, lines 53-56).

Claims 1, 4-5, 8-10, 14 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Heinemann *et al.*(FEMS Microbiology Letters, 2000, vol. 190, "Purification and characterization of a surface-binding protein from *Lactobacillus Fermentum* RC-14 that inhibits adhesion of *Enterococcus faecalis* 1131", pages 177-80.)

The claims are drawn to an *L. fermentum* strain, and components thereof, which has certain properties, including the inhibition of pathogens.

The cited reference discloses a *L. fermentum* which appears to be identical to the presently claimed strain (see, e.g., Abstract, since it similarly inhibits pathogens. The referenced microorganism appears to be identical to the presently claimed strain and is considered to anticipate the claimed microorganism or organic components thereof since it is of the same species as that of the microorganism claimed and is taught to be effective against the same types of pathogens. An "organic component" includes any lipid, any carbohydrate, any amino acid, any protein and various other organic compounds and/or compositions. Consequently, the claimed strain and components thereof appear to be anticipated by the reference.

In the alternative, even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed strain would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

The site of isolation is not indicative of the properties of the strains compared. The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' cultured strains differ and, if so, to what extent, from the strains discussed in the references. Accordingly, inasmuch as the examiner has established that the prior art strain, which is of the same species *Lactobacillus fermentum* as that claimed, likewise shares the property of being able to be effective against the same types of pathogens, she has reasonably demonstrated a reasonable likelihood/possibility that the compared strains are either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing non-obviousness by objective evidence shifted to Applicants. Applicants have not met that burden.

Moreover, Applicant has not demonstrated on this record that any component of the sonicated strain of interest is novel over the reference.

Applicant argues the properties of an allegedly unique strain. However, claim 1 is directed to "A biologically pure culture of **a** *Lactobacillus fermentum* **variant** VRI 003". It is at least ambiguous whether the claim encompasses a specific strain.

In addition, dependent claims are directed to compositions comprising an unidentified amount of the same strain(s) OR of any organic component of the variant. There is nothing on this record to suggest or demonstrate that unidentified organic components "**a** *Lactobacillus fermentum* **variant** VRI 003" distinguish over the components of the prior art strain.

Therefore the rejection is deemed proper and it is adhered to.

Claims 1, 4-5, 8-10, 14-15 and 33-35 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mikelsaar *et al.* (WO03/002131).

The claims are drawn to an *L. fermentum* strain, and components thereof, which has certain properties, including the inhibition of pathogens.

The cited reference discloses a *L. fermentum* which appears to be identical to the presently claimed strain (see, e.g., pages 7 and 9, Tables, as well as page 8, lines 20-22), since it similarly inhibits pathogens and triggers immune modulation through anti-oxidative effects. The referenced microorganism appears to be identical to the presently claimed strain and is considered to anticipate the claimed microorganism or components thereof since it is of the same species as that of the microorganism claimed and is taught to be effective against the same types of pathogens. An "organic component" includes any lipid, any carbohydrate, any amino acid, any protein and various other organic compounds and/or compositions.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a Novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Furthermore, the composition is claimed as a product-by-process. Since the U.S. Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the

applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433.
Consequently, the claimed strain and components thereof appear to be anticipated by the reference.

In the alternative, even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed strain would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

The Appendix E has been fully considered. However, the alleged differences in antibiotic resistance are not borne out by the data in this Appendix, since the antibiotics recited in Mikelsaar *et al.* are not mentioned with any specificity in the document proffered. The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' cultured strains differ and, if so, to what extent, from the strains discussed in the references. Accordingly, inasmuch as the examiner has established that the prior art strain, which is of the same species *Lactobacillus fermentum* as that claimed, likewise shares the property of being able to be effective against the same types of pathogens, she has reasonably demonstrated a reasonable likelihood/possibility that the compared strains are either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing non-obviousness by objective evidence shifted to Applicants. Applicants have not met that burden.

Moreover, Applicant has not demonstrated on this record that any component of the sonicated strain of interest is novel over the reference.

Applicant argues the properties of an allegedly unique strain. However, claim 1 is directed to "A biologically pure culture of **a** *Lactobacillus fermentum* **variant** VRI 003". It is at least ambiguous whether the claim encompasses a specific strain.

In addition, dependent claims are directed to compositions comprising an unidentified amount of the same strain(s) OR to any organic component of the variant. There is nothing on this record to suggest or demonstrate that unidentified organic components "**a** *Lactobacillus fermentum* **variant** VRI 003" distinguish over the components of the prior art strain.

Therefore the rejection is deemed proper and it is adhered to.

Claims 1, 4-5, 8-10, 14 and 33-35 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Blomberg *et al.* (Applied and Environmental Microbiology, 1993, vol. 59(1), "Inhibition of Adhesion of *Escherichia coli* K88 to Piglet Ileal Mucus by *Lactobacillus* spp.", pages 34-39.)

The claims are drawn to an *L. fermentum* strain, and a component thereof, which has certain properties, including antimicrobial effects.

The cited reference discloses a *L. fermentum* which appears to be identical to the presently claimed strain (see, e.g., page 39 since it has antimicrobial effects). The referenced microorganism appears to be identical to the presently claimed strain and is considered to anticipate the claimed microorganism or a component thereof since it is of the same species as that of the microorganism claimed and is taught to be effective against the same types of pathogens. An "organic component" includes any lipid, any carbohydrate, any amino acid, any protein and various other organic compounds and/or compositions.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a Novolac color developer.

The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Furthermore, the composition is claimed as a product-by-process. Since the U.S. Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433.
Consequently, the claimed strain and components thereof appear to be anticipated by the reference.

In the alternative, even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed strain would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

The site of isolation is not indicative of the properties of the strains compared. The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' cultured strains differ and, if so, to what extent, from the strains discussed in the references. Accordingly, inasmuch as the examiner has established that the prior art strain, which is of the same species *Lactobacillus fermentum* as that claimed, likewise shares the property of being able to be effective against the same types of pathogens, she has reasonably demonstrated a reasonable likelihood/possibility that the compared strains are either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing non-obviousness by objective evidence shifted to Applicants. Applicants have not met that burden.

Moreover, Applicant has not demonstrated on this record that any component of the sonicated strain of interest is novel over the reference.

In addition, dependent claims are directed to compositions comprising an unidentified amount of the same strain(s) OR to any organic component of the variant. There is nothing on this record to suggest or demonstrate that unidentified organic components "**a** *Lactobacillus fermentum* **variant** VRI 003" distinguish over the components of the prior art strain.

Therefore the rejection is deemed proper and it is adhered to.

Claims 1, 4-11, 14-15 and 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heinemann *et al.* taken with Mikelsaar *et al.,* and Paul *et al.* and further taken with Matusuzaki *et al.* for the reasons as stated in the last Office action and the further reasons below.

The Heinemann *et al.*, Mikelsaar *et al.* and Matusuzaki *et al.* references are discussed *supra.*

The references differ from the invention as claimed in that the addition of a prebiotic such as a gum or a beta glucan is not disclosed. However, Paul *et al.* adequately demonstrate that the administration of *L. fermentum* in conjunction with prebiotics such as oligosaccharides, inulin or beta-glucans is old and well known in the art (See, e.g., col. 9, lines 27-34). The provision of various formulations is disclosed at col. 15, lines 65 et seq.. The "agglomerated" material is deemed to substantially constitute a tablet. Moreover Matusuzaki *et al.* disclose tablets for organic component administration.

In addition, the use of sonication or homogenization to disrupt cells is old and well known in the art.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a Novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Furthermore, the composition is claimed as a product-by-process. Since the U.S. Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a

sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433.
Consequently, the claimed strain and components thereof appear to be anticipated by the reference.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the *L. fermentum* compositions of Heinemann *et al.* and/or Mikelsaar *et al.* by providing them in conjunction with additives other than in liquid dairy formulations, such as oligosaccharides, inulin or beta-glucans for their well known properties of containing fiber and essential nutrients and in a dried form, such as tablets, as suggested by the teachings of Matsuzaki *et al.* and Paul *et al.* for the expected benefit of providing *L. fermentum* compositions providing dietary fiber and essential nutrients in a formulation that are stable and easy to administer or organic components thereof in suitable pharmaceutically useful compositions.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

As noted *supra,* the site of isolation is not indicative of the properties of the strains compared. In addition, the alleged differences in antibiotic resistance are not borne out by the data in this Appendix, since the antibiotics recited in Mikelsaar *et al.* are not mentioned with any specificity in the document proffered. The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' cultured strains differ and, if so, to what extent, from the strains discussed in the references. Accordingly, inasmuch as the examiner has established that the prior art strain, which is of the same species *Lactobacillus fermentum* as that claimed, likewise shares the property of being able to be effective against the

same types of pathogens, she has reasonably demonstrated a reasonable likelihood/possibility that the compared strains are either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing non-obviousness by objective evidence shifted to Applicants. Applicants have not met that burden.

Moreover, Applicant has not demonstrated on this record that any component of the sonicated strain of interest has unexpected properties.

In addition, dependent claims are directed to compositions comprising an unidentified amount of the same strain(s) OR to any organic component of the variant. There is nothing on this record to suggest or demonstrate that unidentified organic components "**a** *Lactobacillus fermentum* **variant** VRI 003" distinguish over the components and/or strains of the prior art strain.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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